

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Regorafenib hydrate

April 21, 2026

Therapeutic category

Other antitumor agents

Non-proprietary name

Regorafenib hydrate

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Hyperammonaemia</u> <u>Hyperammonaemia may occur even in the absence of abnormal hepatic function. If disturbed consciousness is observed, measurement of ammonia levels should be considered.</u>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.